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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,797	02/17/2004	David Munn	275.00100101	1508

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MUETING, RAASCH & GEBHARDT, P.A.
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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,797	MUNN ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 11/14/06
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Per telephone conversation with Nancy Johnson (see attached Interview Summary), the Restriction Requirement mailed 10/25/2006 is hereby vacated and replaced with the Restriction Requirement detailed below.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-14 and 33, drawn to methods of treating cancer by administering an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 419. NOTE: If Group I is elected, claims 1-2 and 8-12 will only be examined insofar as they are drawn to a method of treating cancer. **Please also note Election of Specie Requirement detailed below.**

II. Claims 1-2, 8-12, 15-31 and 38-40, drawn to methods of treating infections by administering an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 419. NOTE: If Group II is elected, claims 1-2 and 8-12 will only be examined insofar as they are drawn to a method of treating an infection. **Please also note Election of Specie Requirement detailed below.**

III. Claims 32 and 34, drawn to methods of augmenting the rejection of tumor cells, and reducing tumor size by administering an inhibitor of indoleamine-2,3-dioxygenase, classified in class 514, subclass 419. **Please also note Election of Specie Requirement detailed below.**

IV. Claims 35 and 37, drawn to methods of augmenting the rejection of tumor cells and reducing tumor size with a combination of an inhibitor of indoleamine-2,3-dioxygenase and radiation therapy, classified in class 514, subclass 419. **Please also note Election of Specie Requirement detailed below.**

V. Claim 36, drawn to a method of treating cancer with a combination of an inhibitor of indoleamine-2,3-dioxygenase and radiation therapy, classified in class 514, subclass 419. **Please also note Election of Specie Requirement detailed below.**

VI. Claims 41-43, drawn to a method of treating a subject receiving a bone marrow transplant by administering an inhibitor of indoleamine-2,3-dioxygenase and radiation therapy, classified in class 514, subclass 419. **Please also note Election of Specie Requirement detailed below.**

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III, IV, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions do not have overlapping patient populations, have different effects, and have different modes of operation. Groups I, II, III, IV and VI have different patient populations, requiring the treatment of cancer, infections, augmentation of tumor cell rejection, and the treatment of patients receiving a bone marrow transplant, respectively. These patient populations do not overlap in scope and are patentably distinct. For example, one skilled in the art looking to treat an infection would not look for methods of treating cancer, and *vice versa*. Patients having cancer, an infection, tumors, and those receiving a bone marrow transplant are distinct patient

populations, requiring different diagnosis and treatment. Further, the etiologies of these conditions are different and would require different searches.

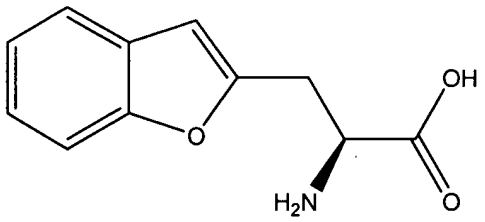
Further, the inventions have different modes of operation and effects. For example, the treatment of a bacterial infection requires elimination of the bacteria whereas treatment of cancer requires inhibiting cancer cell growth. The effect of treating a patient receiving a bone marrow transplant is distinct from that of treating a patient with cancer or an infection. Groups I/II/III and IV/V have different modes of operation. For example, the claims of Groups IV/V require administration of an inhibitor of indoleamine-2,3-dioxygenase and radiation therapy, whereas the claims of Groups I/II/III only require administration of inhibitor of indoleamine-2,3-dioxygenase.

The Groups are similarly classified only because the patent classification system does not have separate classifications for distinct conditions to be treated. Instead, inventions relating to body-affecting compositions and treatment are classified according to the active agent. In this case, the Groups have been classified as a tryptophan derivative as the active agent as there is no classification for "an inhibitor of indoleamine-2,3-dioxygenase". However, the inventions would require separate searches because a search of, for example, a tryptophan derivative for treating cancer is not the same as a search for a tryptophan derivative in the treatment of an infection.

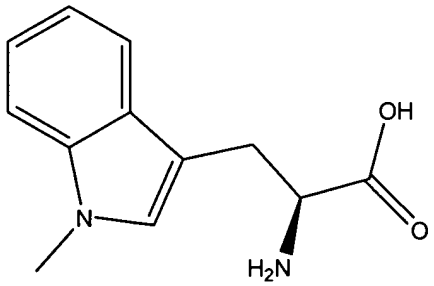
These inventions are independent or distinct for the reasons given above. There would be a serious burden on the examiner if restriction were not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter. Restriction for examination purposes as indicated is proper.

Election of Species Requirement Upon Election of <u>any</u> of <u>Groups I-VI</u>

This application contains claims directed to the following patentably distinct species: the multitude of compounds encompassed by "inhibitor of indoleamine-2,3-dioxygenase." The species are independent or distinct because there is no common core of the claimed genus and to search the entire scope of the claimed genus would present an undue search burden on the examiner. Each inhibitor of indoleamine-2,3-dioxygenase would be separately classified depending on the structure. As no structural characteristics are provided in the specification, it would be an undue burden to search the entire scope of the claimed genus. The instant claims disclose several inhibitors of indoleamine-2,3-dioxygenase, for example:



3-benzofuranyl-alanine



1-methyl-tryptophan

The only commonality of the recited species is the amino acid core. Clearly, to search for any and all "inhibitors of indoleamine-2,3-dioxygenase" would be an undue burden.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-8, 10-11 and 13-42 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Election of Species Requirement Upon Election of Group I

This application contains claims directed to the following patentably distinct species: the multitude of compounds encompassed by "additional therapeutic agent." The species are independent or distinct because there is no common core of the claimed genus and to search the entire scope of the claimed genus would present an undue search burden on the examiner. Each "therapeutic agent" would be separately classified depending on the structure. As no structural characteristics are provided in the specification, it would be an undue burden to search the entire scope of the claimed genus. For example, the instant claims disclose two separate *sub-genera* of "additional therapeutic agents" (chemotherapeutic agents and radiation therapy). There is no common structural feature that could be used to search the entire genus encompassed by "additional therapeutic agent". Clearly, to search for any and all "additional therapeutic agent[s]" would be an undue burden on the examiner. Applicants are required to elect a single *sub-genus* of additional therapeutic agent (*e.g.* chemotherapeutic agents or radiation) **as well as** a single *species* of therapeutic agent from the elected *sub-genus* (*e.g.* a specific chemotherapeutic agent).

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 8, 10-14 and 33 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Election of Species Requirement Upon Election of Group II

This application contains claims directed to the following patentably distinct species: A) the multitude of infections encompassed by "infection" and B) the multitude of compounds encompassed by "additional therapeutic agent."

With respect to "infections", the species are independent or distinct because the term "infection" encompasses a multitude of *sub-genera* of infections with different etiologies and treatment regimes. For example, infections include viral, bacterial, parasitic, and fungal infections. It would be an undue burden to search the entire scope of the claimed genus "infection" because each type of infection has a different patient population and treatment regimen. Applicants are required to elect a single *sub-genus* of infection (*e.g.* bacterial, fungal,

viral, etc.) **as well as** a single *species* of infection from the elected *sub-genus* (*e.g.* a specific bacterial infection or viral infection).

With respect to "additional therapeutic agent", the species are independent or distinct because there is no common core of the claimed genus and to search the entire scope of the claimed genus would present an undue search burden on the examiner. Each "therapeutic agent" would be separately classified depending on the structure. As no structural characteristics are provided in the specification, it would be an undue burden to search the entire scope of the claimed genus. For example, the instant claims disclose additional therapeutic agents that include the *sub-genera* "vaccine", "cytokine", "antiviral agent", "antibiotic" and "antimicrobial agent". There is no common structural feature that could be used to search the entire genus encompassed by "additional therapeutic agent". Clearly, to search for any and all "additional therapeutic agent[s]" would be an undue burden on the examiner. Applicants are required to elect a single *sub-genus* of additional therapeutic agent (*e.g.* vaccine, cytokine, antibiotic, etc.) **as well as** a single *species* of therapeutic agent from the elected sub-genus (*e.g.* a specific vaccine, cytokine, antiviral agent, etc.).

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2, 8-12, 15-31 and 38-40 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Election of Species Requirement Upon Election of Group III

This application contains claims directed to the following patentably distinct species: the multitude of compounds encompassed by the genus "antineoplastic chemotherapeutic agent." The species are independent or distinct because there is no common core of the claimed genus and to search the entire scope of the claimed genus would present an undue search burden on the examiner. There is no common structural feature that could be used to search the entire genus encompassed by "antineoplastic chemotherapeutic agent". Clearly, to search for any and all "antineoplastic chemotherapeutic agent[s]" would be an undue burden on the examiner. Applicants are required to elect a single *species* of chemotherapeutic agent for examination (*e.g.* a specific chemotherapeutic agent).

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32 and 34 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Summary of Species Election Requirements

Due to the number of separate specie elections required in this Office Action, examiner submits the following summary:

If Group I is elected for prosecution, applicants are further required to elect: A) a single specie of inhibitor of indoleamine-2,3-dioxygenase; B) a *sub-genus* of "additional therapeutic agent" (*i.e.* chemotherapeutic agent or radiation); and C) a single *specie* of chemotherapeutic agent if the sub-genus of chemotherapeutic agent is elected.

If Group II is elected for prosecution, applicants are further required to elect: A) a single specie of inhibitor of indoleamine-2,3-dioxygenase; B) a *sub-genus* of "additional therapeutic agent" (*i.e.* cytokine, vaccine, antibiotic, etc.); and C) a single *specie* from the sub-genus elected in B) (*i.e.* a specific vaccine, cytokine, antiviral agent, etc.).

If Group III is elected for prosecution, applicants are further required to elect: A) a single specie of inhibitor of indoleamine-2,3-dioxygenase, and B) a single *specie* of chemotherapeutic agent (*e.g.* fluorouracil, doxorubicin, etc.).

If any of Groups IV, V or VI are elected for prosecution, applicants are only further required to elect a single specie of inhibitor of indoleamine-2,3-dioxygenase.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR § 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson, Ph.D.
Patent Examiner
AU 1614

Phyllis Spivack
12/15/06

December 14, 2006